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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,423	10/22/2003	Joseph Oneal	APROG.0101	6169
22858	7590	02/07/2006	EXAMINER	
CARSTENS & CAHOON, LLP P O BOX 802334 DALLAS, TX 75380			KRISHNAN, GANAPATHY	
			ART UNIT	PAPER NUMBER

1623

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,423

Applicant(s)

ONEAL ET AL.

Examiner

Ganapathy Krishnan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15 and 16 is/are allowed.
- 6) ☒ Claim(s) 1-14 and 17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/8/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Page 1 of the specification recites the names of three Inventors whereas the Oath/Declaration filed on 4/6/2004 recites only two inventors. Appropriate correction is required.

Claim Objections

Claims 8 and 15 are cause of the following informalities: In claims 8 and 15 recite the terms “at least one of”. The proper Markush language, “selected from the group consisting of” should be recited. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is drawn to a method of maintaining urinary tract health in the face of an infection. It is not clear what applicants intend by this recitation. For the purpose of prosecution the claim is examined as drawn to a method of treating urinary tract infection. A similar interpretation of claim 8 is also in order.

Claim 5 recites the term affect. It is not clear what applicants intend by this term.

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Claims 12-14 and 17 recite the term equivalents. In the absence of a recitation of what the equivalents are the claims are rendered indefinite.

Claim 12 contains the trademark/trade name Cratavin. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe an active agent and, accordingly, the identification/description is indefinite.

Claims that depend from a rejected base claim that are unclear/indefinite are also rendered unclear/indefinite and are rejected for the same reasons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benedict et al (US 6,753,319) in combination with Carella et al (WO 97/29763) and Iwahi et al (J. Med. Microbiol., 1982, 15(3), 303-316).

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Benedict et al teach that D-Mannose has been widely used for the treatment of urinary tract infections (col. 1, lines 27-29). However, Benedict et al do not teach administering a dosage of one to two teaspoons of D-mannose to a patient three times a day with meals for one to two weeks or until the symptoms subside or a dose that contains approximately 2 grams of mannose.

Carella et al teach the use of D-mannose in a composition for the promotion of a healthy environment in urogenital tracts and for treating urogenital disorders (page 2, lines 7-10 and 16-17; page 5, lines 15-16). Plant extracts (interpreted as herbs that affect urinary tract, as instantly claimed in claim 5) are also included in the composition (page 8, lines 23-27). The compositions can be administered as tablets, capsules (page 10, lines 7-10) and can contain 5 to about 75% per

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unit dose (page 6, lines 22-25). According to Carella additional ingredients and dosages can be readily ascertained using routine experimentation (page 14, lines 32-35). This means that the art recognizes that the dosages can be varied or frequency of administration adjusted till symptoms subside.

Iwahi et al teach that d-mannose is potent in inhibiting viral adhesion to the urinary tract (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer d-mannose containing other herbs to treat urinary tract infection and maintain urinary tract health since the use of mannose for the said treatment is seen to be taught in the prior art. One of ordinary skill in the art would be motivated to use d-mannose as the active agent since d-mannose is potent in preventing viral adhesions to the urinary tract as taught by Iwahi et al.

Conclusion

1. Claims 1-14 and 17 are rejected.
2. Claims 15-16, drawn to a composition comprising D-mannose, and one of crataeva nurvala, white willow bark and pollen extract are seen to be free of prior art.

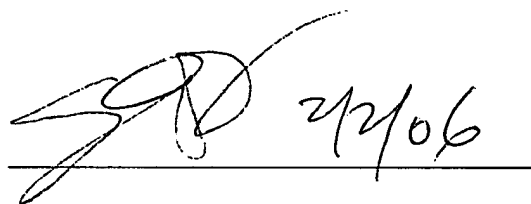
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathy Krishnan whose telephone number is 571-272-0654. The examiner can normally be reached on 8.30am-5pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GK

A handwritten signature, likely of Shaojia A. Jiang, is written over a horizontal line. To the right of the signature, the date "2/2/06" is handwritten.

Shaojia A. Jiang
Supervisory Patent Examiner
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